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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,687	08/19/2003	Haim Aviv	87754-7500	6729

28765 7590 12/05/2005

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/644,687	Applicant(s) AVIV ET AL.	
	Examiner Taofiq A. Solola	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6, 8-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-6, 8-24 are pending in this application.

Claim 7 is cancelled.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/05 has been entered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 15-16, 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kloog et al., US 5,284,867.

Kloog et al., disclose the instantly claimed compound (HU-211), essentially free of the (3R,4R) enantiomer, various pharmaceutical formulations (compositions) for various types of administrations (columns 4-5) and methods of use for treating neurological disorders. The formulation is emulphor or emulsions and may contain antioxidants, preferably the antioxidant is α -tocopherol. See example 3, column 12 and column 13, lines 1-5. Kloog et al., also disclose various % combinations of the emulsions in column 13, lines 5 to 23.

Applicant should note that the phraseology "essentially free of the (3R,4R) enantiomer" is deemed (3S,4S) enantiomer is in enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer absent a showing to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kloog et al., US 5,284,867.

Applicant claims the (3S,4S) enantiomer of compound I having enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer, the composition and method of use for treating various neurological disorders. The composition comprise co solvents such as polyoxyl 35 castor oil from 30-80 % W/W, ethanol from 20-70 % W/W and 0.001-0.1 % w/w of edetic acid. Applicant also claims composition having 0.1-5 % W/W of α -tocopherol.

Determination of the scope and content of the prior art (MPEP §2141.01)

Kloog et al., teach the instantly claimed compound (HU-211), essentially free of the (3R,4R) enantiomer, various pharmaceutical formulations (compositions) for various types of administrations (columns 4-5) and methods of use for treating neurological disorders. The composition comprise co solvents such as ethanol, glycerol, PEG and PPG. Kloog et al., also teach composition having 0.02 % W/W of α -tocopherol. See columns 12-13.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Kloog et al., is that applicant claims the instant compound having (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer, while Kloog et al., teach the compound as essentially free of the (3R,4R) enantiomer. Also, applicant is claiming co solvents such as polyoxyl 35 castor oil from 30-80 %

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W/W, ethanol from 20-70 % W/W and 0.001-0.1 % W/W of edetic acid, while Kloog et al., do not teach polyoxyl 35 castor oil, edetic acid or % W/W of ethanol.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, there is no evidence that the compound of Kloog et al., does not have (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer. Even if the instantly claimed compound is substantially purer than the compound of Kloog et al., and there are new and novel properties, functions or utilities arising from the higher level of purity, such would not make the instant invention patentable over the prior art of Kloog et al. Something old does not become new upon discovery of new properties (e.g. purification level), functions or utilities. *In re Best*, 562 F.2d 1252; 195 USPQ 430 (CCPA, 1977). Also, the addition of an inert carrier, such as co-solvents, to a non-patentable compound is not patentable. *Ibid*. Claiming 20-70 % ethanol and 0.1-5 % α -tocopherol are obvious modifications available to the special preference of an artisan. They are mere optimization of variables, which are not patentable absent unexpected result due to each variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller*, 22 F.2d 454, 105 USPQ 233 (CCPA, 1955).

Therefore, the instant invention is prima facie obvious from the teaching of Kloog et al. One of ordinary skill in the art would have known to claim compound of formula I as (3S,4S) enantiomeric excess of at least 99.90 % over the (3R,4R) enantiomer at the time this invention was made. The motivation is from the teaching of Kloog et al., that the compound is essentially free of the (3R,4R) enantiomer.

Response to Argument and Declaration

Based on the study and declaration by Avihai Yacovan, applicant contends that "the Mechoulam sample" shows adverse effect. This is not persuasive because the study is not a

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true side-by-side comparison. The Mechoulam sample does not represent a true Kloog et al sample. The difference between 99.4 and 99.9 percent is within experimental error and/or design.

This is an RCE of the same applicant's Application. All claims are drawn to the same invention and have been finally rejected on the grounds and art of record in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this RCE. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

November 23, 2005